

FIRST IMPRESSIONS QUARTERLY™

A Publication for Sleep Disorders Professionals



TWO RECENT ANNOUNCEMENTS BY IMPORTANT STANDARDS AND POLICY ORGANIZATIONS DESERVE THE ATTENTION OF SLEEP PRACTITIONERS.

AASM PRACTICE PARAMETER CHANGES

The March issue of the journal *SLEEP*¹ features a recent update to the Practice Parameters for the Use of CPAP and Bi-Level devices in treating patients with sleep apnea. The update is provided by the American Academy of Sleep Medicine (AASM). In it, the Standards of Practice Committee members present a list of practice parameters for the treatment of Obstructive Sleep Apnea (OSA) with continuous positive airway pressure therapy (CPAP), bi-level positive airway pressure therapy and automatic self-adjusting positive airway pressure therapy (APAP).

Recommendations are broken down into 3 main categories: **Standard Recommendation** which holds a high level of clinical evidence and should be generally accepted as patient care strategy; **Guideline Recommendation** which holds a moderate amount of clinical evidence and could be implemented; and **Option Recommendation** which holds a low level of clinical evidence and may have uncertain outcomes in clinical use or holds conflicting expert opinions.

Several of the new recommendations from the committee members include the following:

CPAP should be objectively monitored to help assure utilization. (Standard)

An overwhelming number of recent studies found that patients over-report their use of CPAP therapy and that objective measurement is required for an accurate assessment. CPAP and Bi-level units are available that objectively monitor and report patient adherence data. Historically providers have been reluctant to use

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AASM PRACTICE PARAMETER CHANGES *(continued from page 1)*

these units because they are more costly. However, The Centers for Medicare and Medicaid Services (CMS) announced a new code for reimbursement for objective data. More information will be released later this year by CMS.

Close follow-up for PAP usage and problems with OSA is indicated to determine if treatment is effective, accepted and to troubleshoot problems. (Standard)

This change was made after review of 61 studies that examined the management of patients on CPAP. Seventeen studies, labeled as well-designed trials (Level 1), demonstrated that PAP therapy adherence is established in the first few months of use. It was also found that if therapy issues arise in the first few months (especially mask comfort and nasal conditions) and are not addressed, the patient will often discontinue therapy use altogether.

Bi-Level is an optional therapy in some OSA cases. (Guideline)

If CPAP therapy fails, the authors suggest alternative therapies (like bi-level therapy) for a non compliant patient, especially for those who require high pressures or those who experience difficulty with exhalation against a fixed CPAP pressure. This is also consistent with new CMS guidelines highlighting the use of Bi-Level therapy for patients that are non tolerant or non responsive to traditional CPAP therapy.

Heated humidification should be a standard practice to improve CPAP utilization. (Standard)

The authors reference three Level 1 studies showing improved utilization, with the addition of heated humidification. Three other studies demonstrated improved adherence to therapy with heated humidification vs. non humidification when using CPAP.

CPAP therapy is no longer recommended but is now optional for patients with mild OSA. (Option)

This change reflects the recent release of practice parameters for oral appliances that recommend oral appliances be used to treat snoring and mild OSA. The practice parameters

highlighted that oral appliances can be used for patients who fail CPAP therapy or prefer an oral appliance vs. CPAP therapy for mild OSA. *Sleep 2006; 29 (2) 240 – 243.*

If you would like to read more concerning the new practice parameters, please reference: *Sleep 2006; 29(3):375-380.*

CMS CHANGES REIMBURSEMENT POLICY

The Centers for Medicare and Medicaid Services (CMS) recently announced changes to reimbursement policy for respiratory assist devices (RAD). Since patients with sleep disorders may be covered under Medicare, the policy changes, effective January 1, 2006, warrant careful review.

Following are some of the highlights:

AHI Determination by Polysomnography (PSG)

The new guidelines define the apnea/hypopnea index (AHI) as “the number of episodes of apnea and hypopnea per hour based on 2 hours of sleep reported by PSG using actual recorded hours of sleep without positive airway pressure therapy reported on the PSG.” The previous guideline definition did not specify the length of time of actual hours of sleep under PSG.

Central Sleep Apnea Re-defined

Central Sleep Apnea is defined as an apnea/hypopnea index (AHI) greater than 5, with central apneas/hypopneas accounting for 50% or more of the total AHI; and central apneas/hypopneas are greater than or equal to 5 times per hour with patient symptoms of either excessive sleepiness or disrupted sleep.

Complex Sleep Apnea

The definition of Complex Sleep Apnea is new to the RAD policy. It is described as the emergence or persistence of central apneas or hypopneas upon exposure to CPAP therapy or an E0470 device when obstructive events have disappeared. The patients will show predominately obstructive or mixed apneas during the diagnostic sleep study greater than or equal to 5 times per hour.

The new policy also eliminates the need for desaturation. The previous policy required desaturation <88% for longer than 5 minutes, while the patient stayed on stable FIO₂, in order to identify complex sleep apnea or central sleep apnea.

For more information regarding the changes in policy please visit your DMERC website. Complete policies can be found under “Supplier Manual” on each site:

Region A: http://www.tricenturion.com/content/lcd_current_dyn.cfm

Region B: www.adminastar.com/Providers/DMERC/MedicareManuals/suppliermanual.htm

Region C: [http://www.palmettogba.com/palmetto/providers.nsf/\(Docs\)/85256D580043E754852571790043FEB2?OpenDocument](http://www.palmettogba.com/palmetto/providers.nsf/(Docs)/85256D580043E754852571790043FEB2?OpenDocument)

Region D: www.cignamedicare.com/dmerc/dmsm/index.html

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sleep vip program™
Update

**TWO NEW SLEEP
COORDINATORS JOIN
THE SLEEP VIP TEAM**

Denise Konovich and Jo Ann Vinkovich have joined the Sleep VIP Team as Sleep Coordinators. Both have years of experience in working with Respironics customers, have an in-depth understanding of the Company's sleep therapy and diagnostic product lines and can help offer solutions to suit your needs.

Denise Konovich brings a diverse skill set to her new position. In her six years at Respironics she has held several positions of increasing responsibility—from manufacturing to customer support—that give her a unique perspective on customer needs.

Jo Ann Vinkovich has worked at Respironics for eight years, first as a Customer Service Representative, and later as a Marketing and Sales Liaison.

“I’m so excited to be working directly with our Sleep VIPs,” notes Jo Ann. “It’s a chance to really develop strong relationships with some of our most important customers.”

Denise agrees, “The opportunity to take the knowledge that we’ve developed over the years and see it work for our customers, is great. It helps us to see how what we offer can make a difference to our customers and their patients.”

You can contact Denise and Jo Ann, Monday through Friday 8:30 a.m. to 5:00 p.m. EST at 1-800-345-6443, Option 2 then Option 5 or at sleepvip@respironics.com.

MASK FITTING TIPS

ComfortLite™ 2 Nasal Mask

When adjusting the ComfortLite 2 with Pillows or Direct Seal cushions, always use the vertical adjuster (*Figure 1*) or the angle adjuster (*Figure 2*) to move the cushion closer to the nostrils. Never use the vertical metal band (*Figure 3*). This can cause the vertical metal band to dislodge from the exhalation chamber (*Figure 4*). If this happens, simply slide the metal band back into the slot on the exhalation chamber (*Figure 5*).

If you have a patient with long or silky hair, you may want to try putting the backstrap of the headgear under the patient's hair (*Figure 6*). This will provide a more comfortable and stable fit.



Figure 1

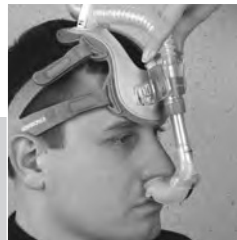


Figure 2



Figure 3



Figure 4



Figure 5

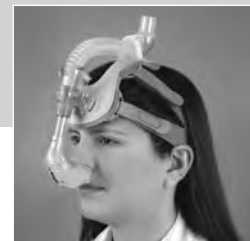


Figure 6

If you would like more tips on how to find the best fit for the ComfortLite 2, you can download the following literature from our Marketing Resources Library at www.respironics.com. You can also call customer service at 1-800-345-6443 to order a hardcopy.

Helpful Tips for Successful Use – ComfortLite 2	PN 1035470
ComfortLite 2 Clinician Fitting Guide	PN 1029161
ComfortLite 2 Patient Fitting Guide	PN 1033070

RESPIRONICS RESOURCE CORNER

OSA Awareness and Education Posters and Brochure

To help increase awareness of Obstructive Sleep Apnea (OSA) and educate patients about the disorder, Respironics has developed a set of two posters and a brochure for use in your sleep center, in homecare provider locations, or in physician offices.

An “awareness” poster calls attention to the fact that excessive sleepiness may indicate a serious breathing disorder. It provides an overview of OSA and encourages the reader to talk to their doctor if they think they may have the disorder. A second “treatment” poster focuses on safe, effective therapy for OSA and how treatment may help patients live a healthier, more productive life.

A new 8-page brochure provides additional details about OSA, including signs and symptoms, diagnosis, treatment and tips for living with the disorder. A holder is included so that the brochure can be attractively displayed on a tabletop.

To order these free educational tools, please call Customer Service and ask for the part numbers listed below:

PN 1034672 – OSA Patient Education Posters; Set of 2

PN 1034744 – OSA Patient Education Brochures; Includes 50 brochures and 1 holder

Great Awakening Presentation

The Great Awakening is a PowerPoint presentation designed to help raise awareness and educate communities on the prevalence and dangers of OSA. This easy-to-understand presentation touches on the entire OSA care process from definition to diagnosis to treatment. The disk also includes instructions on how to locate a target audience and conduct the presentation. It also includes support materials such as introduction and confirmation letters, presentation checklist, presentation evaluation, fast fact sheets and a thank you letter.



To order a free copy of the Great Awakening, please call Customer Service and ask for Part Number 1035776.

SLEEP TECH TIPS:



Recently one of our night techs brought a quicker way to clean electrodes to the lab. Use any standard coffee pot (minus the coffee). Fill the coffee pot with water, and run it as if you were making coffee. Once the water is hot, pour it over the electrodes. This dissolves the paste quickly, and saves time and energy from scrubbing the leads one by one. Then disinfect according to your lab's protocol. Works great!

Gay Bourgeois, RPSGT

Premier Sleep Medicine Center
Baton Rouge, LA

We have dedicated the “Sleep Tech Tips” section to helpful hints that you would like to share with your peers.* If you have discovered ways to improve diagnostic procedures, to make your patients more comfortable during their sleep study, or to increase patient compliance, email them to us at marketing-communications@respironics.com. Please put “Sleep Tech Tips” in the subject line and be sure to include your name, title, the name of your facility and phone number. If we use your tip, we will send you a small gift of appreciation.

* By submitting your tips you are granting Respironics the right to publish and use your information in any way Respironics deems appropriate, without obligation beyond the free gift mentioned here.

ASK THE RESPIRONICS EXPERT

Q: How can I use patient therapy data on AHI, Snore and Leak to improve patient treatment and adherence to therapy?

A: Respiroics SmartCard® technology and Encore® Pro software for data capture and reporting enables healthcare professionals to objectively measure and assess patients adherence with their PAP treatment. With critical parameters of AHI, Snore and Leak, clinicians can maximize their abilities to quickly and accurately identify issues associated with therapy efficacy and patient acceptance of therapy.

Studies show that a patient's acceptance of therapy for long-term regular use is typically established in the first 30 days of treatment.¹ Many healthcare professionals focus on this time to closely monitor and respond to patient adherence patterns. Objective usage patterns captured from download technology such as the Encore® Pro SmartCard® provide helpful information on usage patterns based on metrics such as total therapy hours and number of sessions lasting more than 4 hours. Although useful, this data only enables a clinician to understand whether or not a patient is using the sleep system. It does not provide insight on the efficacy of the therapy sessions in treating the SDB or in the case of a non-compliant patient, why a patient may not be using therapy regularly.

With the addition of AHI, Snore and Leak parameters, a healthcare professional can monitor and respond with more accuracy and insight to resolve issues associated with efficacy of therapy over short and long term as well as with issues associated with patient compliance.

With the ability to assess AHI over the course of a night or given time period, clinicians can validate if effective treatment is maintained at the prescribed pressure. With the additional Leak parameter, the clinician can further establish if therapy effectiveness is influenced by mask issues.

The Leak parameter also provides important insight on why a patient may not be adhering and accepting therapy into a nightly routine. Large leak rates suggest

mask issues associated with poor seal. Common mask intervention protocols can be quickly implemented to assess proper mask fit, size and type in order to achieve optimal seal.

With this advanced level of insight, clinicians can better respond to patients' needs and ultimately enable improved long term outcomes for their patients.

1. **Determinants of Nasal CPAP Compliance.** C. Stepnowsky Jr, MR Marler, S. Ancoli-Israel. Sleep Medicine 2002 (3) ;239-247.

Q: Your mask product manuals state that all of your mask materials are latex free, but is there a way to know what materials a specific mask is made of?

A: Yes. Respiroics has a Mask and Accessories Materials List, part number 1035985. To order the list contact Customer Service at 1-800-345-6443. If you need further explanation or if you have any questions related to our masks, please contact our Product Support group at 1-800-345-6443.

UPCOMING TRADESHOWS AND EVENTS

Heart Failure Society of America
September 10 - 13
Seattle, WA

CHEST
October 21 - 24
Salt Lake City, UT

MEDTRADE
September 19 - 21
Atlanta, GA

New England Polysomnographic Society
4th Annual Summer Conference
August 24 - 25

American Sleep Association
October 15 - 17
Chicago, IL

Hyannis, MA

If you wish to view this issue or any previous issues of *First Impressions Quarterly* visit www.firstimpressions.respiroics.com.

RESEARCH RECAP

IMPORTANT CLINICAL FINDINGS PRESENTED AT THE ATS AND APSS CONCERNING ACCEPTANCE, COMFORT AND RESULTS WITH PATIENTS ON OSA THERAPY.

Spring time allows for new data to emerge between poster sessions held at the American Thoracic Society (ATS) meeting in San Diego and the meeting of the Associated Professional Sleep Societies (APSS) in Salt Lake City, Utah. With the development of new technology, these national meetings allow physicians to discuss and present the latest research on Sleep Apnea treatments and demonstrate the impact technology can have on a patient's acceptance, tolerance and response to therapeutic interventions such as Auto PAP Therapy with C-Flex™ and Auto Bi-level Therapy.

There were several studies published evaluating the impact of Auto CPAP with C-Flex on the cognition, acceptance and effectiveness of therapy.

- Dr. Mulgrew, et. al. studied OSA patients to confirm efficacy of the Remstar®Auto CPAP with C-Flex™ and to determine if patients preferred Auto CPAP to traditional CPAP. Patients were randomly assigned and blinded to the treatment modality.
 - The results demonstrated patients placed on the RemStar Auto with C-Flex had a significant improvement in slow wave sleep.
 - Patients treated with RemStar Auto with C-Flex required fewer technician interactions than patients on traditional CPAP therapy.¹
- Dr. Castronovo, et. al evaluated the impact of PAP treatment on cognitive function in 50 OSA patients after 2 months of Auto CPAP therapy with C-Flex.
 - The patients demonstrated a significant improvement in cognitive function which may be related to treatment compliance.
- Dr. Castronovo presented a second study suggesting the use of alternative forms of PAP therapy for patients who are not tolerant to traditional CPAP therapy during therapy titration.²

Auto Bi-Level Therapy is a new option for patients who have been identified with OSA. This technology combines both Bi-level and Auto-titrating therapy to treat patients with OSA.

- Dr. Wylie and Dr. Grover conducted a multi-center study to determine the efficacy of therapy using BiPAP® Auto compared to traditional bi-level therapy, on 17 newly diagnosed OSA patients with no prior exposure to PAP therapy.
 - The study demonstrated the BiPAP Auto treated OSA as effectively as manually titrated, conventional bi-level positive airway pressure therapy³.
- A second study by Dr. Stollo, et. al demonstrated that BiPAP Auto effectively controlled OSA and did not impact respiratory control, ventilation or contribute to the development of complex sleep apnea⁴.

Bibliography:

1. Mulgrew, A., et.al. AJRCCM 2006; 3; a869
2. Castronova, VE., et.al. Sleep 2006; 29 a190 and a 213
3. Wylie P, et.al. Sleep 2006; 29; a196
4. Stollo, P.J., et.al. AJRCCM 2006; 3; a871 and Sleep 2006: 29; a209



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NEW PRODUCTS

COMFORTLITE™ 2 NASAL MASK

As the newest addition to Respironics' Comfort Series™ of Masks, the ComfortLite™ 2 packs more comfort features into a smaller, lighter mask. With multiple cushion options and no facial pressure points, this new mask does even more to meet the comfort and lifestyle needs of patients looking for a minimal-contact mask. To learn more visit www.comfortseries.respironics.com.



THE NEW HOME FOR C-FLEX™ — RESPIRONICS REMSTAR® M SERIES

Respironics introduces the new REMstar® M Series — the only complete line of sleep therapy systems that provides the proven patient comfort of C-Flex™ and ease of use in a sleek, modern design. C-Flex technology tracks the patient's breathing and lowers the amount of pressure delivered during exhalation for more comfortable therapy. With its small size, three easy-to-use primary control buttons and more lifestyle-oriented design, the REMstar M Series is targeted at improving the patient's acceptance of therapy. Features such as ramp, integrated humidification and an improved monitoring system are incorporated into the design. Several REMstar M Series models are available to meet the needs of providers and patients. To learn more, visit www.mseries.respironics.com.

